E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2021-0068; FRL-8732-06-OCSPP]

Certain New Chemicals; Receipt and Status Information for November 2021

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is required under the Toxic Substances Control Act (TSCA) to make information publicly available and to publish information in the *Federal Register* pertaining to submissions under TSCA Section 5, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. This document covers the period from 11/01/2021 to 11/30/2021.

DATES: Comments identified by the specific case number provided in this document must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2021-0068 and the specific case number for the chemical substance related to your comment, through the Federal eRulemaking Portal at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Jim Rahai, Project Management and Operations Division (MC 7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8593; email address: *rahai.jim@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

This document provides the receipt and status reports for the period from 11/01/2021 to 11/30/2021. The Agency is providing notice of receipt of PMNs, SNUNs and MCANs (including amended notices and test information); an exemption application under 40 CFR part 725 (Biotech exemption); TMEs, both pending and/or concluded; NOCs to manufacture a new chemical substance; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review.

EPA is also providing information on its web site about cases reviewed under the amended TSCA, including the TSCA section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-*

pre-manufacture-notices. This information is updated on a weekly basis.

B. What is the Agency's authority for taking this action?

Under TSCA, 15 U.S.C. 2601 *et seq*., a chemical substance may be either an "existing" chemical substance or a "new" chemical substance. Any chemical substance that is not on EPA's TSCA Inventory of Chemical Substances (TSCA Inventory) is classified as a "new chemical substance," while a chemical substance that is listed on the TSCA Inventory is classified as an "existing chemical substance." (See TSCA section 3(11).) For more information about the TSCA Inventory please go to: *https://www.epa.gov/tsca-inventory*.

Any person who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, or to manufacture or process a chemical substance in a non-exempt manner for a use that EPA has determined is a significant new use, is required by TSCA section 5 to provide EPA with a PMN, MCAN or SNUN, as appropriate, before initiating the activity. EPA will review the notice, make a risk determination on the chemical substance or significant new use, and take appropriate action as described in TSCA section 5(a)(3).

TSCA section 5(h)(1) authorizes EPA to allow persons, upon application and under appropriate restrictions, to manufacture or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a)(2), for "test marketing" purposes, upon a showing that the manufacture, processing, distribution in commerce, use, and disposal of the chemical will not present an unreasonable risk of injury to health or the environment. This is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to: *http://www.epa.gov/oppt/newchems.*

Under TSCA sections 5 and 8 and EPA regulations, EPA is required to publish in the **Federal Register** certain information, including notice of receipt of a PMN/SNUN/MCAN (including amended notices and test information); an exemption application under 40 CFR part 725 (biotech exemption); an application for a TME, both pending and concluded; NOCs to

manufacture a new chemical substance; and a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review.

C. Does this action apply to me?

This action provides information that is directed to the public in general.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

E. What should I consider as I prepare my comments for EPA?

1. *Submitting confidential business information (CBI)*. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2.

2. *Tips for preparing your comments*. When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

II. Status Reports

In the past, EPA has published individual notices reflecting the status of TSCA section 5 filings received, pending or concluded. In 1995, the Agency modified its approach and streamlined the information published in the **Federal Register** after providing notice of such changes to the public and an opportunity to comment (See the **Federal Register** of May 12, 1995, (60 FR 25798) (FRL-4942-7). Since the passage of the Lautenberg amendments to TSCA in 2016, public interest in information on the status of section 5 cases under EPA review and, in particular, the final determination of such cases, has increased. In an effort to be responsive to the regulated community, the users of this information, and the general public, to comply with

the requirements of TSCA, to conserve EPA resources and to streamline the process and make it more timely, EPA is providing information on its web site about cases reviewed under the amended TSCA, including the TSCA section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices.* This information is updated on a weekly basis.

III. Receipt Reports

For the PMN/SNUN/MCANs that have passed an initial screening by EPA during this period, Table I provides the following information (to the extent that such information is not subject to a CBI claim) on the notices screened by EPA during this period: The EPA case number assigned to the notice that indicates whether the submission is an initial submission, or an amendment, a notation of which version was received, the date the notice was received by EPA, the submitting manufacturer (i.e., domestic producer or importer), the potential uses identified by the manufacturer in the notice, and the chemical substance identity.

As used in each of the tables in this unit, (S) indicates that the information in the table is the specific information provided by the submitter, and (G) indicates that this information in the table is generic information because the specific information provided by the submitter was claimed as CBI. Submissions which are initial submissions will not have a letter following the case number. Submissions which are amendments to previous submissions will have a case number followed by the letter "A" (e.g., P-18-1234A). The version column designates submissions in sequence as "1", "2", "3", etc. Note that in some cases, an initial submission is not numbered as version 1; this is because earlier version(s) were rejected as incomplete or invalid submissions. Note also that future versions of the following tables may adjust slightly as the Agency works to automate population of the data in the tables.

Table I. – PMN/SNUN/MCANs Approved* from 11/01/2021 to 11/30/2021

Case No.	Version	Received Date	Manufacturer	Use	Chemical Substance
J-21-0020	2	11/05/2021	Cinder Biological, Inc.	(G) Enzyme production	(G) CinderBio-1
J-21-0021	2	11/05/2021	Cinder Biological, Inc.	(G) Enzyme production	(G) CinderBio-1
J-21-0022	2	11/05/2021	Cinder Biological, Inc.	(G) Enzyme production	(G) CinderBio-1
J-21-0023	2	11/05/2021	Cinder Biological, Inc.	(G) Enzyme production	(G) CinderBio-1
J-21-0024	2	11/05/2021	Cinder Biological, Inc.	(G) Enzyme production	(G) CinderBio-1
J-21-0025	2	11/05/2021	Cinder Biological, Inc.	(G) Enzyme production	(G) CinderBio-1
J-22-0001	1	10/26/2021	CBI	(G) Chemical production	(G) Chromosomally-modified Saccharomyces cerevisiae
J-22-0002	1	10/26/2021	CBI	(G) Chemical production	(G) Chromosomally-modified Saccharomyces cerevisiae
J-22-0003	1	10/26/2021	CBI	(G) Chemical production	(G) Chromosomally-modified Saccharomyces cerevisiae
J-22-0004	1	10/26/2021	CBI	(G) Chemical production	(G) Chromosomally-modified Saccharomyces cerevisiae
J-22-0005	1	10/26/2021	CBI	(G) Chemical production	(G) Chromosomally-modified Saccharomyces cerevisiae
J-22-0006	1	10/26/2021	CBI	(G) Chemical production	(G) Chromosomally-modified Saccharomyces cerevisiae
J-22-0007	1	10/27/2021	CBI	(G) Production of DNA for use in internal manufacturing	(G) Strain of Escherichia coli modified with genetically-stable, plasmid-borne DNA for the production of plasmid-borne DNA
P-19-0134A	8	11/04/2021	CBI	(S) Binder for moisture cure coatings	(G) [5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane], [Poly[oxy(methyl-1,2-ethanediyl)], .alpha.-hydro-.omega.-hydroxy-, polymer with 1,6-diisocyanatohexane], polymer with [Poly(oxy-1,4-butanediyl), .alpha.-hydro-.omega.-hydroxy-], [Cyclic amine - ketone adduct, reduced], and

					[1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-]
P-20-0060	5	11/10/2021	CBI	(S) Solvent-based pigmented one- and two-component polyurethane coatings Automotive Refinish General Industrial Coil	(G) Bismuth Carboxylate complexes
P-20-0096A	5	11/09/2021	Solenis LLC	(G) Use in papermaking process	(G) Unsaturated dicarboxylic acid polymer with 2-(dialkylamino)alkyl-alkyl-alkanoate, N, N-dialkyl-alkene amide, 2-propenamide and salt of alkyl-substituted alkene sulfonate
P-20-0127A	5	11/09/2021	Kuraray America, Inc.	(S) Industrial Solvent	(S) 2H-Pyran, tetrahydro-4-methyl-
P-20-0182A	2	11/19/2021	Eastman Chemical Company, Inc	(G) Plasticizer for PVC formulations	(S) 1,4-Benzenedicarboxylic acid, bis[2-(2-butoxyethoxy)ethyl] ester (9 CI)
P-21-0017A	2	11/05/2021	Sumitomo Chemical Advanced Technologies LLC	(S) Substance used to improve physical properties in rubber products	(G) [(Substituted-carbomonocyclic) amino] oxoalkenoic acid, inorganic salt
P-21-0049A	5	11/18/2021	CBI	(G) Monomer	(G) Alkanoic acid, polyhalo-(halo-oxo-alkenyl)oxyalkyl ester
P-21-0050A	5	11/18/2021	CBI	(G) Monomer	(G) Alkenoic acid, halo-polylhaloalkyl ester
P-21-0089A	4	11/09/2021	CBI	(G) Emulsifier	(G) Lignin, modified, reaction products with alkylamine by-products, hydrochlorides
P-21-0090A	4	11/09/2021	CBI	(G) Component in paving formulations	(G) Lignin, modified, reaction products with alkylamine by-products
P-21-0138A	3	11/15/2021	LG Energy Solution Michigan Inc	(S) Electrode material for use in the manufacture of batteries	(G) Lithium metal oxide
P-21-0172A	6	11/04/2021	Silco, Inc.	(S) Moisture reactive polymer for use in sealants	(G) Siloxanes and Silicones, di-Me, trimethoxysilyl group

				and coatings	terminated
P-21-0173A	3	11/09/2021	ICM Products Inc.	(G) Additive for finishing of textiles/fabrics	(G) Siloxanes and silicones polyether, polymer with aliphatic isocyanate, 2-dimethylaminoethanol and polyglycol ether
P-21-0213	2	10/28/2021	ICM Products Inc.	(G) Textile finishing agent	(G) Siloxanes and Silicones, alkyl methyl, dimethyl
P-21-0218	3	11/17/2021	Honeycomb Techno Research USA Inc	(G) Electric Molding	(G) Phenol biphenylene polycondensate
P-22-0001	1	10/04/2021	CBI	(G) Raw material for manufacturing chemicals	(G) Alkane, disubstituted
P-22-0008	2	11/22/2021	CBI	(G) Biocatalyst used in a variety of products	(S) .beta.-N-Acetylhexosaminidase
P-22-0010	1	11/17/2021	H.B. Fuller Company	(S) This chemical is being used as part of an industrial adhesive	(G) Amino alkanoic acid, N-[3-(Trimethoxysilyl)Propyl]-, 3-(Trimethoxysilyl)Propyl ester
P-22-0012	1	11/24/2021	CBI	(G) Photolithography	(G) Sulfonium, tricarbocyclic-, 2-heteroatom-substituted-4-(halocarbocyclic)carboxylate (1:1)
SN-21-0012	3	11/15/2021	Showa Denko Materials (America), Inc.	(S) Epoxy molding compound	(S) Oxirane, 2,2'-[methylenebis[(2,6-dimethyl-4,1-phenylene)oxymethylene]]bis-

*The term ‘Approved’ indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission prior to the start of the 90 day review period, and in no way reflects the final status of a complete submission review.

In Table II of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the NOCs that have passed an initial screening by EPA during this period: The EPA case number assigned to the NOC including whether the submission was an initial or amended submission, the date the NOC was received by EPA, the date of commencement provided by the submitter in the NOC, a notation of the type of amendment (e.g., amendment to generic name, specific name, technical contact information, etc.) and

chemical substance identity.

Table II. – NOCs Approved* From 11/01/2021 to 11/30/2021

Case No.	Received Date	Commencement Date	If Amendment, Type of Amendment	Chemical Substance
J-21-0006	11/08/2021	11/08/2021	N	(G) Modified saccharomyces cerevisiae
J-21-0011	11/11/2021	10/28/2021	N	(G) Saccharomyces cerevisiae fermenting C5 sugars, modified
J-21-0016	11/08/2021	10/11/2021	N	(G) Modified saccharomyces cerevisiae
P-01-0925A	11/11/2021	04/16/2004	Update generic chemical name	(G) 1,2-Ethanediamine, n-[3-trialkoxysilyl) propyl]reaction products with dialkoxymethyl[3-(oxyanylalkoxy) propyl] silane and trialkoxy [3-(oxyanylalkoxy) propyl] silane
P-01-0926A	11/11/2021	04/16/2004	Update generic chemical name	(G) Alkenoic acid, 2-methyl-, butyl ester, polymer with 2-hydroxy-3-phenoxypropyl 2-propenoate and methyl 2-methyl-2-propenoate
P-16-0539A	11/24/2021	09/17/2020	Update generic chemical name	(G) Sulfonium, tricarbocyclic-, alpha, alpha, beta, beta-polyhalopolyhydrospiro[4,7-methano-1,3-heteropolycyclic-2,2-cycloalkane]-5-alkanesulfonate (1:1)
P-16-0548A	11/03/2021	07/09/2020	Update generic chemical name	(G) Aromatic sulfonium, [([aromatic]-thio)phenyl]phenyl-, fluoro-alkyl phosphate
P-17-0206	11/05/2021	07/30/2020	Multiple chemicals in a single submission were split out	(G) Imino alkane amine phosphate
P-17-0206	11/05/2021	07/30/2020	Multiple chemicals in a single submission were split out	(G) Imino alkane amine phosphate
P-17-0343A	11/01/2021	04/09/2018	Update generic chemical name	(G) Heteropolycyclic-alkanol, carbomonocycle-alkanesulfonate

P-18-0012A	11/02/2021	08/31/2021	Update generic chemical name	(G) Vegetable oil, polymer with alkyl dialcohol, polyglycol, aromatic dicarboxylic acid and vegetable oil
P-18-0023A	11/03/2021	09/30/2021	Update generic chemical name	(G) 1,2-propanediol, 3-[(2-ethylhexyl)oxy]- hydrogen phosphate
P-18-0035	11/01/2021	06/10/2020	Multiple chemicals in a single submission were split out	(S) Propenoic acid, 2-methyl-, 1,3-dioxolan-4-ylmethyl ester
P-18-0035A	11/01/2021	06/10/2020	Multiple chemicals in a single submission were split out	(S) 2-propenoic acid, 2-methyl-, 1,3-dioxan-5-yl ester
P-18-0273	11/11/2021	10/20/2021	N	(S) 1,4-cyclohexanedicarboxylic acid, 1,4-bis(2-ethylhexyl) ester
P-18-0282	11/01/2021	10/06/2021	N	(G) Fatty acid ester, polyether, diisocyanate polymer,
P-19-0020A	11/02/2021	08/27/2021	Update generic chemical name	(G) Alkylphenol, reaction products with carbon dioxide, distn. residues from manuf. of alkylphenol derivs. and calcium alkylphenol derivs.
P-21-0078	11/17/2021	11/03/2021	N	(G) Phenol, polymer with alkyl-(alkylalkylenyl)cyclohexene, mixed dialkylcyclohexadienes, mixed alkyl-(alkylalkylidene)cyclohexenes and 3,7,7-trimethylbicyclo[4.1.0]hept-3-ene,

*The term ‘Approved’ indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission.

In Table III of this unit, EPA provides the following information (to the extent such information is not subject to a CBI claim) on the test information that has been received during this time period: The EPA case number assigned to the test information; the date the test information was received by EPA, the type of test information submitted, and chemical substance identity.

Table III. – Test Information Received from 11/01/2021 to 11/30/2021

Case No.	Received Date	Type of Test Information	Chemical Substance

P-16-0206	10/27/2021	Fish Acute Toxicity Test, Freshwater and Marine (OECD Test Guideline 203)	(G) Formaldehyde ketone condensate polymer
P-16-0543	11/02/2021	Exposure Monitoring Report (September 2021)	(G) Halogenophosphoric acid metal salt
P-16-0543	11/02/2021	Exposure Monitoring Report (June 2021)	(G) Halogenophosphoric acid metal salt
P-20-0014	11/01/2021	*Pimephales Promelas* (Fathead minnow) Acute Semi-Static Renewal 96-Hour Definitive Toxicity Test using OCSPP 850.1085 Fish Acute Toxicity Test mitigate by Humic Acid	(G) Sugars, polymer with alkanetriamine
P-20-0014A	11/18/2021	Disassociation Constants in Water (OECD Test Guideline 112)	(G) Sugars, polymer with alkanetriamine

If you are interested in information that is not included in these tables, you may contact EPA's technical information contact or general information contact as described under **FOR FURTHER INFORMATION CONTACT** to access additional non-CBI information that may be available.

Authority: 15 U.S.C. 2601 *et seq*.

Dated: December 21, 2021.

Pamela Myrick,

Director,

Project Management and Operations Division,

Office of Pollution Prevention and Toxics.

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